REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 35-36, 38, 40-44, 46-49, 51-54, and 58-61 pending and under consideration. For the reasons discussed below it is believed that all rejections presently of record have been overcome. Allowance of this application is therefore solicited.

Claim Rejections under 35 USC §103

Claims 35-36, 38, 40-44, 46-49 and 52-54 stand rejected under 35 USC §103(a) over Roger et al., (Ceramide-coated Balloon Catheters Limit Neointimal Hyperplasia After Stretch Injury in Carotid Arteries in view of Barry et al. (6306166) in view of Fischell (6120533). This rejection is traversed.

The Examiner asserts that the Roger et al. reference prefers ceramide but "blanketly discloses lipophilic bioactive material in general...". Office Action, page 2. The Examiner equates the "bioactive lipid" teaching of Roger et al. with "lipophilic bioactive material". Office

Action, page 3, bottom paragraph. The Roger et al. teaching of its "bioactive lipid" is not a teaching of any "lipophilic bioactive material". Lipids are a specific class of naturally-occurring compounds that are principle components of cells. The aim of Roger et al. is to study a very specific class of lipid materials for limiting neointimal hyperplasia. In doing this, Roger et al. discloses forming a "lipid gel" on the latex balloon of an embolectomy catheter. See page 283, left column under "Lipid Therapeutics". Roger et al. does not pertain to finding new ways to deliver paclitaxel or any other non-lipid bioactive agents. Paclitaxel is not a lipid, and cannot form the "lipid gel" of Roger et al.

Barry et al., on the other hand, expressly teaches the need to contain the drug within a polymer layer, such that it is later released at the treatment site by diffusion from the polymer layer. See, e.g., column 4, line 46 to column 5, line 26. Upon the asserted foundation that Roger et al. teaches the use of any lipophilic bioactive material, the Examiner pulls paclitaxel from the disclosure of Barry et al. and transfers it to Roger et al. This analytical leap is erroneous for at least two reasons.

First, the foundational assumption that Roger et al. teaches the use of any lipophilic bioactive material is incorrect, as discussed above. The teachings of Roger et al. are specific to testing the performance and activity of a narrow set of lipid compounds, and do not invite one of ordinary skill to begin substituting other divergent compounds. Second, this substitution ignores the entire import of Barry et al.: a polymer layer is required to contain the drug and then later release it at the delivery site by diffusion out of the polymer layer. References must be considered as a whole, and in order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. *In re: Avery*, 518 F2d 1228, 186 USPQ 161 (CCPA 1975). In making a combination the fact finder must "guard against temptation to read into the prior art the teachings of the invention in issue". *Graham v. John Deere*, 383 US 1, at 36 (1966). In the present case it is not obvious that paclitaxel could be separated from the context of Barry et al. and substituted into Roger et al. to provide a workable alternative to ceramide. The rejection is therefore improper.

Additionally, the reliance on Fischell for teaching an angioplasty balloon with folds is noted. Fischell does not repair the deficiencies outlined above. Also, there is error in the Examiner's assertion that the incorporation of Fischell into the rejection would "inherently meet the portions of the dried layer containing agent are positioned in the folds, since the balloon would be coated prior to folding, so that is [*sic*, it] could freely unfold when inflated".

A finding that a feature is inherent in the prior art requires that the feature necessarily occur. Mere possibilities are not enough. Roger et al. teaches the use of a latex balloon, which expands by stretching. Barry et al. itself teaches the possibility of applying drug to a balloon in its deflated condition. See column 8, lines 38-41. Accordingly, the Examiner's finding of inherency at page 4 of the Office Action is incorrect. Relatedly, the Examiner's assertions at page 2 of the Office Action with respect to the positioning of the claimed coating on the surface and that "a coated stent when folded meets these limitations" is not accepted. The claimed folds are of a balloon, not of a stent.

For at least the foregoing reasons, the rejections of claims 35-36, 38, 40-44, 46-49 and 52-54 over the combination of Roger et al. in view of Barry et al. in view of Fischell are improper, and should be withdrawn.

Turning to the Examiner's comments regarding certain specific dependent claims, with regard to claim 36, it is noted that Roger et al. is silent as to inflation time, and no inherency or obviousness can be drawn from the reference in regard to the claims. With regard to claim 38, this claim requires that the dried layer contain a diagnostic agent. The Examiner notes the "dye" in Roger et al; however, it clear that this dye is used during later immersion of the balloon and is not present in the lipid material when the drying is complete to form the lipid gel. Regarding claim 40, the Examiner states that "angioplasty is on a coronary artery". While angioplasty can be conducted on a coronary artery, not all angioplasties are. This is evident in Roger et al, which conducts an angioplasty on a carotid artery. With regard to claims 41, 44, 46-48 and 54, the Examiner comments about the dosing disclosed in Barry et al., and extrapolates from there. It is noted, however, that the dosing in Barry et al. is for

delivery via a drug-loaded polymer layer, and the Examiner's remarks on obviousness improperly ignore this distinction. With regard to claim 43, the Examiner does not explain why the named polymers would be considered to be functionally equivalent to the latex used in the Roger et al. balloon. With regard to claim 48, again, the Examiner's remarks improperly ignore that Barry et al. deals with delivery of an amount of drug via diffusion from a drug-loaded polymer layer.

For these further reasons, withdrawal of the subject rejections is solicited.

Claim 51 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al. in view of Barry et al (6369039) in view of Fischell (6120533) as applied to claim 40 above and in further view of Palasis et al (6369039). Palasis et al. is relied upon for teaching a guide wire lumen in a balloon catheter. It has not been and could not be relied upon to fill the deficiencies of the references noted above with respect to claim 49, from which claim 51 depends. Withdrawal of this rejection is therefore also solicited.

New Claims

New claims 58-61 have been added. They are supported by the original claims and throughout the specification, and add no new matter to the application. These claims are also believed to be patentably distinct from the references relied upon due to deficiencies in the combinations clear from the above discussions. Consideration and allowance of these new claims is also solicited.

Conclusion

This response is made in order to address the Office Action in an expedient fashion. No admission is made as to the propriety of the positions stated in the Office Action regarding the claims or prior art. It is submitted that this response overcomes all rejections. Allowance of this application containing claims 35-36, 38, 40-44, 46-49, 51-54, and 58-61 is thus solicited.

Request for Interview

If, for any reason, the Examiner is unable to allow the application as presently amended, request is hereby

made for an in-person or telephonic interview prior to any further office action in the case. The undersigned attorney can be contacted to arrange the interview.

Respectfully submitted,

By 

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